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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,017	01/08/2001	James F. Zucherman	KLYC 1000USN SRM	9622

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FLIESLER DUBB MEYER & LOVEJOY, LLP
FOUR EMBARCADERO CENTER
SUITE 400
SAN FRANCISCO, CA 94111

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,017

Applicant(s)

ZUCHERMAN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/35/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-98, 101-103 and 105-113 is/are rejected.
- 7) ☒ Claim(s) 99, 100 and 104 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7-9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 94 and 113 are objected to because of informalities, which can be corrected as follows: In claim 94, line 5, "is" should be deleted. In claim 113, line 4, "processes" should be replaced by ~~process~~. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 106 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2, "said removing step" lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

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published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 90-98, 101, and 109-113 are rejected under 35 U.S.C. 102(b) as being anticipated by Breard (5,011,484). With respect to claims 90-92, Breard discloses, in col. 2, lines 9-15; col. 3, line 14-31; col. 4, lines 10-28; and figures 1-5; a method for stabilizing a spinous process (A) relative to another spinous process, where a device (1) is introduced between and conformed to the processes. Also with respect to claims 91, 92, and 98, the pre-formed device is made of an elastic or resilient material with a shape memory (polytetrafluoroethylene or PTFE) and has a cantilevered configuration (at lips, 4 and 5), which can be made to conform to a process in-situ with the artificial ligament (L). With respect to claims 93, 94, and 101 the device has cavities (2, 3, 8) fillable with materials, such as the artificial ligament or portions of the spinous processes. With respect to claims 95-97 and 109-111: Since the device is made of PTFE, it inherently provides shock-absorbing, compressible surfaces, which dampen motion of the processes and spread forces in contact with the device. With respect to claims 112 and 113, figures 6 and 7 disclose the introduction of a device (1a) between spinous processes without alteration of the processes.

6. Claims 102, 103, 105, 106, and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (5,549,679). Kuslich discloses, in figure 12 and in col. 9, lines 41-52, the introduction of a device (146) in the vicinity of or about spinous processes, where the device has a first, loose configuration and a second, rigid configuration; and where the device is not connected to the processes.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 105 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich. Kuslich discloses the invention substantially as claimed, but does not specifically disclose an introduction tool in the method; nor does Kuslich disclose a device with a first temperature in a first configuration and a second temperature in a second configuration. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply an introduction tool (e.g., forceps) to insert an adjust Kuslich's device in a patient. An introduction tool provides a convenient means to manipulate the device in a confined surgical environment. Also, it would be obvious to render the device with a first temperature in a first configuration and a second temperature in a second configuration. The first temperature of the loose,

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device materials (see col. 12, lines 16-23) can be room temperature or at a refrigerated temperature before its introduction into a patient, while the second temperature of rigidified materials can be body temperature after introduction of the device in a patient.

Allowable Subject Matter

9. Claims 99, 100, and 104 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method of stabilizing a spinous process relative to another spinous process, where the method includes the introduction of a device between the processes, and where the device is made of a material which changes shape or is reconfigured, while it is between the processes.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lumb et al. (3,648,691) and Kapp et al. (4,554,914) teach devices for attachment to spinous processes. Sava (5,658,286) teaches a device fillable with a material for spinal fixation.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

A handwritten signature in black ink, appearing to read 'J. Woo', is positioned above the printed name of the examiner.

Julian W. Woo
Patent Examiner

July 16, 2002